Moderna Highlights Opportunity of mRNA Vaccines at its First Vaccines Day

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Vaccines create significant value for healthcare systems by preventing infectious disease; despite this, the vast majority of viruses do not have commercial vaccines available, representing a large opportunity

Moderna has demonstrated neutralizing immunogenicity against all eight viruses targeted in clinical trials to date using the Company's innovative vaccine platform

First interim analysis of Phase 1 Zika vaccine candidate (mRNA-1893) study shows that 10 µg and 30 µg dose levels seroconverted 94% and 100% of seronegative participants, respectively, and effectively boosted seropositive participants; both dose levels generally well-tolerated

NIH-led Phase 1 study of mRNA-1273, Moderna's vaccine candidate against the novel coronavirus, continues on track with enrollment of participants at the highest dose

Virtual Vaccines Day to be held at 8:00 a.m. ET on Tuesday, April 14

CAMBRIDGE, Mass.--(BUSINESS WIRE)--Apr. 14, 2020-- Moderna, Inc. (Nasdaq: MRNA), a clinical stage biotechnology company pioneering messenger RNA (mRNA) therapeutics and vaccines to create a new generation of transformative medicines for patients, today is hosting its first Vaccines Day, including presentations highlighting the potential advantages of mRNA vaccines. The Company is also announcing new positive interim Phase 1 data from its Zika vaccine candidate (mRNA-1893). With this data, Moderna's prophylactic vaccines modality now has seven positive Phase 1 readouts, including a combination vaccine against two viruses (hMPV and PIV3; mRNA-1653). The Company has demonstrated neutralizing immunogenicity against all eight viruses targeted to date in its clinical trials. Based on the totality of this clinical experience, earlier this year the Company designated prophylactic vaccines a core modality and is working to accelerate the development of its vaccine pipeline.

The vast majority of human viruses do not have a commercially available vaccine in the United States. This gap includes many long-known viruses, such as cytomegalovirus (CMV) (discovered in 1956), Zika (1962) and Epstein-Barr virus (EBV, 1964), but also includes many emerging novel viruses. Since 1980, an average of two novel viruses that infect humans have been discovered each year. Examples of these novel viruses include HIV 1 (discovered in 1983), Hepatitis C (1989), H1N1 (2009), and SARS-CoV-2 (2019). Moderna's vaccine pipeline has been studied in ten clinical trials to date with more than 1,400 participants. Clinical data demonstrate that Moderna's proprietary vaccine technology has been generally well-tolerated and can elicit durable immune responses to viral antigens. The Company also believes that it has demonstrated the ability to leverage shared technology, digital systems and a flexible manufacturing infrastructure to advance a large portfolio quickly and efficiently.

"We believe that our seven innovative first-in-class mRNA vaccine candidates provide a strong foundation for Moderna and offer a high probability of success when compared to other technologies. In the last several decades, 80 new pathogens have emerged, yet the vast majority of these viruses lack an approved vaccine in the U.S. We believe that vaccines offer a large total addressable market and an opportunity to reduce healthcare costs with a benefit to society through the prevention of devastating illnesses in areas of unmet need," said Stéphane Bancel, Moderna's Chief Executive Officer. "The totality of data from our vaccines platform gives us reason to be optimistic about the prospects for our vaccines to come, including our vaccine against the novel coronavirus."

In an analysis published in *Biostatistics* in April 2019, Dr. Andrew Lo, et al. studied the probability of clinical trial success rates and related parameters of more than 185,000 clinical trials involving 21,000 compounds. This robust analysis compared infectious disease vaccines to other therapeutic areas and found that infectious disease vaccines have an overall 33% probability of success that increases to a 42% probability of success once a Phase 2 study is launched, the highest of all therapeutic areas.

"It's critical for clinical researchers and biopharma investors to evaluate the probability of success when making scientific and economic decisions," said Andrew Lo, Ph.D., Director of MIT's Laboratory for Financial Engineering. "After analyzing more than 185,000 clinical trials involving 21,000 compounds, we found that infectious disease vaccines have the highest probability of clinical success."

Interim Phase 1 Data for Zika Virus Vaccine (mRNA-1893)

All four cohorts (10 µg, 30 µg, 100 µg, 250 µg) of the Phase 1 study of mRNA-1893 have been dosed. An interim analysis of the study reports safety and immunogenicity data from the 10 µg and 30 µg cohorts. Neutralizing antibody titers were assessed using Plaque Reduction Neutralization Test ($PRNT_{50}$) and microneutralization assays (MN), which provide equivalent guidance for interpreting the neutralizing immune response.

Following a two-dose vaccination schedule of mRNA-1893 given 28 days apart, the 10 µg and 30 µg dose levels were both generally well-tolerated, and there were no vaccine-related serious adverse events (SAEs) or adverse events of special interest (AESI). The most frequent solicited adverse reaction was local pain at the injection site. The safety profile did not appear affected by the second vaccination nor a flavivirus-positive baseline serostatus.

The analysis also showed that the 10 µg and 30 µg dose levels induced a neutralizing antibody response in both flavivirus infection-naïve (seronegative) participants and in participants with pre-existing flavivirus antibodies (seropositive), as shown by geometric mean titers and seroconversion rates. Notably, a single vaccination of the 30 µg dose level was sufficient to convert baseline flavivirus seronegative participants. However, there was a clear benefit of a two-dose series given 28 days apart.

In the flavivirus-seronegative group:

- Seroconversion rates after the second vaccination reached 94.4% in the 10 µg dose level and 100% in the 30 µg dose level, based on the $PRNT_{50}$. MN data were consistent with $PRNT_{50}$ data.

In the flavivirus-seropositive group:

- The percentage of participants achieving a 4-fold boost in pre-existing $PRNT_{50}$ titers after the second vaccination reached 50% in the 10 µg dose level and 75% in the 30 µg dose level, based on the $PRNT_{50}$. MN data were consistent with $PRNT_{50}$ data.

“I am encouraged by these interim Phase 1 data showing the ability of mRNA-1893 to elicit a strong neutralizing antibody response,” said Tal Zaks, M.D., Ph.D., Chief Medical Officer at Moderna. “Our Zika program, along with our continued work on a vaccine candidate against the novel coronavirus, underscore our commitment to improving global public health through developing mRNA vaccines to prevent the spread of infectious diseases.”

This project has been funded in whole or in part with Federal funds from the Department of Health and Human Services; Office of the Assistant Secretary for Preparedness and Response; Biomedical Advanced Research and Development Authority, under Contract No. HHSO100201600029C. It was granted Fast Track designation by the U.S. Food and Drug Administration (FDA) in August 2019. Moderna owns worldwide commercial rights to mRNA-1893.

About Moderna’s Prophylactic Vaccines Modality

Moderna scientists designed the Company’s prophylactic vaccines modality to prevent infectious diseases. More than 1,400 participants have been enrolled in Moderna’s infectious disease vaccine clinical studies under health authorities in the U.S., Europe and Australia. Based on clinical experience across seven Phase 1 studies, the Company has designated prophylactic vaccines a core modality and is working to accelerate the development of its vaccine pipeline.

Moderna currently has nine development candidates in its prophylactic vaccines modality, including:

Vaccines against respiratory infections

- Respiratory syncytial virus (RSV) vaccine for older adults (mRNA-1777 and mRNA-1172 or V172 with Merck)
- RSV vaccine for young children (mRNA-1345)
- Human metapneumovirus (hMPV) and parainfluenza virus type 3 (PIV3) combination vaccine (mRNA-1653)
- Novel coronavirus (SARS-CoV-2) vaccine (mRNA-1273)
- Influenza H7N9 (mRNA-1851)

Vaccines against infections transmitted from mother to baby

- Cytomegalovirus (CMV) vaccine (mRNA-1647)
- Zika vaccine (mRNA-1893 with BARDA)

Vaccines against highly prevalent viral infections

- Epstein-Barr virus (EBV) vaccine (mRNA-1189)

To date, Moderna has demonstrated positive Phase 1 data readouts for seven prophylactic vaccine candidates (H10N8, H7N9, RSV, chikungunya virus, hMPV/PIV3, CMV and Zika). Moderna’s CMV vaccine candidate is currently in a Phase 2 dose-confirmation study.

Virtual Vaccines Day Today

Moderna will host a virtual Vaccines Day today, Tuesday April 14th, beginning at 8:00 a.m. ET. A live webcast will be available under “Events and Presentations” in the Investors section of the Moderna website at investors.modernatx.com. A replay of the webcast will be archived on Moderna’s website for one year following the presentation.

About Moderna

Moderna is advancing messenger RNA (mRNA) science to create a new class of transformative medicines for patients. mRNA medicines are designed to direct the body’s cells to produce intracellular, membrane or secreted proteins that can have a therapeutic or preventive benefit and have the potential to address a broad spectrum of diseases. The Company’s platform builds on continuous advances in basic and applied mRNA science, delivery technology and manufacturing, providing Moderna the capability to pursue in parallel a robust pipeline of new development candidates. Moderna is developing therapeutics and vaccines for infectious diseases, immuno-oncology, rare diseases and cardiovascular diseases, independently and with strategic collaborators. Moderna has 24 mRNA development candidates in its portfolio across all modalities, with 13 in clinical studies. Five of these programs are in or preparing for Phase 2 studies and the Company is preparing for its first Phase 3 study.

Headquartered in Cambridge, Mass., Moderna currently has strategic alliances for development programs with AstraZeneca PLC and Merck & Co., Inc., as well as the Defense Advanced Research Projects Agency (DARPA), an agency of the U.S. Department of Defense, and BARDA, a division of the Office of the Assistant Secretary for Preparedness and Response (ASPR) within the U.S. Department of Health and Human Services (HHS). Moderna has been named a top biopharmaceutical employer by Science for the past five years. To learn more, visit www.modernatx.com.

Forward Looking Statement

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, as amended, including regarding: the potential for vaccines to be an effective way to address pandemic threats and reduce healthcare costs; the success of data from the Phase 1 study of mRNA-1893; the Company’s development of a potential vaccine against the novel coronavirus (mRNA-1273); the conduct and timing of the Phase 1 study of mRNA-1273; the Company’s potential manufacturing capabilities to advance a large portfolio quickly and efficiently; the ability of the Company’s seven innovative first-in-class mRNA vaccine candidates to provide a strong foundation and offer a high probability of

success for the Company; and the size of total addressable market for the Company's vaccines, if approved. In some cases, forward-looking statements can be identified by terminology such as "will," "may," "should," "expects," "intends," "plans," "aims," "anticipates," "believes," "estimates," "predicts," "potential," "continue," or the negative of these terms or other comparable terminology, although not all forward-looking statements contain these words. The forward-looking statements in this press release are neither promises nor guarantees, and you should not place undue reliance on these forward-looking statements because they involve known and unknown risks, uncertainties, and other factors, many of which are beyond Moderna's control and which could cause actual results to differ materially from those expressed or implied by these forward-looking statements. These risks, uncertainties, and other factors include, among others: the fact that interim Phase 1 data from the Phase 1 study of mRNA-1983 may not be indicative of final data from the study; the results and timing of the Phase 1 study of mRNA-1983; the fact that there has never been a commercial product utilizing mRNA technology approved for use; the fact that the rapid response technology in use by Moderna is still being developed and implemented; the fact that third-party analyses of the probability of clinical trial success have not been prepared by the Company; and those risks and uncertainties described under the heading "Risk Factors" in Moderna's most recent Annual Report on Form 10-K filed with the U.S. Securities and Exchange Commission (SEC) and in subsequent filings made by Moderna with the SEC, which are available on the SEC's website at www.sec.gov. Except as required by law, Moderna disclaims any intention or responsibility for updating or revising any forward-looking statements contained in this press release in the event of new information, future developments or otherwise. These forward-looking statements are based on Moderna's current expectations and speak only as of the date hereof.

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